UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLIE UTTS and CIARA UTTS,	:	
Plaintiffs,	:	Civil Action No. 1:16-cv-05668-DLC
-against-	:	
BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,	:	ORAL ARGUMENT REQUESTED
Defendants.	:	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC.'S MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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Defendants Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer") (collectively, "Defendants") hereby submit this Memorandum in Support of their Motion to Dismiss Plaintiffs' Second Amended Complaint ("SAC") pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). For the reasons discussed below, Plaintiffs' SAC should be dismissed in its entirety.

PRELIMINARY STATEMENT

On July 15, 2016, Plaintiffs filed their original complaint, alleging that Mr. Utts experienced internal bleeding and other injuries as a result of taking Defendants' anticoagulant medication Eliquis (apixaban). Plaintiffs primarily alleged that Defendants failed to warn about the bleeding risk with Eliquis and about the lack of an agent to reverse its anticoagulant effect. Those allegations stood in stark contrast to the Eliquis labeling, which always has contained prominent warnings emphasizing the bleeding risk associated with Eliquis use—the word "bleeding" appears no less than 65 times in the label—and that no method exists to reverse the anticoagulant effect of the medication. Defendants moved to dismiss Plaintiffs' complaint in its entirety, based on federal preemption, adequacy of the warnings, and other grounds.

On December 23, 2016, the Court issued an Order granting Defendants' motion. The Court held that Plaintiffs' design defect claims were preempted by federal law, and it dismissed those claims with prejudice. The Court also dismissed Plaintiffs' warnings claims on federal preemption grounds, finding that Plaintiffs had not alleged that any "newly acquired information" exists to support new or stronger warnings in the FDA-approved Eliquis labeling. The Court gave Plaintiffs an opportunity to amend their pleadings to address this deficiency, as well as to address pleading deficiencies in their manufacturing defect, warranty, fraud, and consumer protection causes of action, all of which the Court dismissed with leave to amend. The Court did not reach Defendants' adequacy of the warnings argument, reserving that until after the preemption issue is resolved.

On January 20, 2017, Plaintiffs filed their First Amended Complaint and Defendants filed their motion to dismiss on February 10, 2017. On February 24, 2017, Plaintiffs filed their Second Amended Complaint. Both of Plaintiffs' amended complaints include a host of new claims and allegations. They do not, however, cure the fundamental deficiencies that underlie Plaintiffs' claims, particularly when viewed in the context of a label that always has warned prominently and clearly of the risk of the very injury alleged by Plaintiffs.

Plaintiffs' Claims Are Preempted. First, Plaintiffs still have not alleged that any "newly acquired information" exists that would have allowed Defendants to independently make any relevant changes to the Eliquis labeling. To be sure, Plaintiffs' SAC references several pieces of post-approval data. But none of those includes any information about the nature, severity, or frequency of the bleeding risk (or any other relevant risk), which is new or different from the explicit and detailed information already included in the FDA-approved labeling. *See* 21 C.F.R. § 314.3(b). Moreover, each of the pieces of data cited by Plaintiffs *post-dates Mr. Utts's alleged injury*, and involves potential risks that have no relationship to Plaintiffs' injury claims. Accordingly, the post-approval data referenced in the amended complaints could not have supported a labeling change pursuant to the Changes Being Effected ("CBE") regulations before Mr. Utts took Eliquis. For this reason, Plaintiffs' warnings claims, which underlie all of their causes of action, should be dismissed on federal preemption grounds. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015); *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

The Eliquis Label Is Adequate As a Matter of Law. Second, while Plaintiffs include a laundry list of new warnings claims and additional details regarding the alleged labeling deficiencies, a careful review of those claims only further supports Defendants' argument that the Eliquis label is adequate as a matter of law. Indeed, the alleged deficiencies outlined in the

amended complaints are at odds with the plain text of the original, FDA-approved Eliquis label, and/or are predicated on design defect claims that were dismissed as preempted under this Court's Order. For that reason also, Plaintiffs' warnings claims should be dismissed. *See Dash v. Roche Labs.*, 74 F.3d 1245 (9th Cir. 1996).

Plaintiffs' Individual Causes of Action Are Inadequately Pled. Third, Plaintiffs still have not corrected the pleading deficiencies that led this Court to dismiss their manufacturing defect, warranty, fraud / negligent misrepresentation, and consumer protection claims. Virtually all of these claims are based on threadbare allegations that are insufficient to create a plausible cause of action. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To the extent that Plaintiffs have attempted to add more specific allegations (for example, with regard to their fraud claims), those allegations are preempted by federal law and/or contradicted by the FDA-approved labeling. Accordingly, each of those causes of action should be dismissed.

As Plaintiffs have now had three bites at the apple, Defendants respectfully request that the Court dismiss their complaint in its entirety and with prejudice.

LEGAL STANDARD FOR A MOTION TO DISMISS

In evaluating a motion to dismiss, federal courts follow the pleading requirements established in *Ashcroft v. Iqbal* and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). "To survive a [Rule 12(b)(6)] motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678. Additionally, "[f]actual allegations must be enough to raise a right to relief above the speculative level[.]" *Twombly*, 550 U.S. at 555. This "plausibility standard" requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. "[A] plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not

do[.]" *Twombly*, 550 U.S. at 555. Although a plaintiff's allegations generally must be accepted as true, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Brown v. Daikin Am. Inc.*, 756 F.3d 219, 225 (2d Cir. 2014). Furthermore, the court need not accept as true "any allegations that are contradicted by documents deemed to be part of the complaint, or materials amenable to judicial notice." *In re Yukos Oil Co. Sec. Litig.*, No. 04 Civ. 5243, 2006 WL 3026024, at *12 (S.D.N.Y. Oct. 25, 2006).

ARGUMENT

I. Plaintiffs' Warning Claims Are Preempted by Federal Law.

As this Court explained in its December 23, 2016 Order, "federal law expressly forbids a manufacturer from changing its label after the label has received FDA approval unless such changes are made pursuant to the CBE [Changes Being Effected] regulation." Order, at 30-31. A manufacturer is permitted to use the CBE process to make "moderate changes" to its label unilaterally (*i.e.*, without prior FDA approval) only if the changes "reflect newly acquired information."[1] 21 C.F.R. § 314.70(c)(6)(iii). Such "newly acquired information" is defined as "data, analyses, or other information *not previously submitted to the Agency*, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (*e.g.*, meta-analyses) *if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA*." 21 C.F.R. § 314.3(b) (emphasis added). Absent plausible allegations that the manufacturer had such "newly acquired information," it is appropriate to dismiss failure-to-warn claims as preempted. Order, at 18, n.6.

In ruling on Defendants' original motion, this Court found that Plaintiffs' "complaint d[id]

[1] A manufacturer cannot make unilateral major changes to the labeling pursuant to the CBE regulation. *See* 21 C.F.R. § 314.70(b). Changes to a boxed warning and to the Medication Guide are considered to be "major changes". *See* 21 C.F.R. § 314.70(b)(2)(v).

not allege that the defendants were in possession of 'newly acquired information' such that they could, pursuant to the CBE regulation, act independently of the FDA to update the Eliquis label." *Id*. at 31. For that reason, the Court held that Plaintiffs' warnings claims, whether based on a theory of negligence or strict liability, were preempted and dismissed those claims, with leave to amend. *See id*. at 31-32. This holding is entirely consistent with Supreme Court precedent in *Wyeth v. Levine* and *PLIVA, Inc. v. Mensing*, and with the First Circuit's holding in *In re Celexa & Lexapro Mktg. & Sales Practices Litig*.

In response, Plaintiffs have now filed two amended complaints, which include a laundry list of new failure-to-warn claims and a new section captioned "Post-Approval Data." *See* SAC ¶¶ 52-70. In that section, Plaintiffs identify four pieces of evidence which they contend constitute "newly acquired information." *See id.* These are: (1) a September 2015 ISMP QuarterWatch report, (2) a 2016 BMJ article, (3) a 2015 JAMA Internal Medicine article, and (4) a 2016 FDA FAERS Signal Report. *See id.* As discussed below, this "Post-Approval Data" is not "newly acquired information" as defined in the CBE regulation and does not provide a basis upon which Defendants could have independently made any changes to the Eliquis product labeling, particularly during the period relevant to Plaintiffs' claims.

A. Plaintiffs' Post-Approval Data Post-Date Mr. Utts's Injury.

Mr. Utts allegedly "suffered a severe gastrointestinal bleeding event" on or about July 16, 2014. *See* SAC ¶¶ 15-16. Each of the four pieces of post-approval data cited by Plaintiffs post-dates Mr. Utts's alleged injury. The ISMP QuarterWatch Report was published on September 23, 2015, and includes analyses of adverse event data from the third and fourth quarter of 2014. *See* Ex. 1 (ISMP QuarterWatch), at 1. The BMJ Article was accepted for publication on May 20, 2016, *see* Ex. 2 (Larsen 2016), at 1, and the JAMA Internal Medicine Article was published online on February 9, 2015. *See* Ex. 3 (Seife 2015), at 567. Finally, the FDA report is based on

adverse event data collected between July and September 2016. *See* Ex. 4 (FDA Signal Report), at 1. Accordingly, none of these data could have served as the basis for a CBE label change during the period of time relevant to Plaintiffs' claims (between the initial Eliquis approval in December 2012 and Mr. Utts's alleged injury in July 2014). On that basis alone, the Court should dismiss Plaintiffs' SAC with prejudice.

B. Plaintiffs' Post-Approval Data Do Not Provide Any New Information About the Nature of the Bleeding Risk with Eliquis.

While Plaintiffs include a laundry list of warnings claims in their SAC, the essence of all the claims is that Defendants failed to adequately warn about the bleeding risk with Eliquis. Thus, to provide the basis for a CBE label change relevant to their claims, any post-approval data would have to include new information about the nature and/or severity of the bleeding risk associated with Eliquis use. None does.[2]

The ISMP Report Does Not Include Any New Information Regarding the Bleeding Risk Associated with Eliquis Use. Plaintiffs contend that the ISMP adverse event analysis "shows a higher than indicated risk of a bleeding event with or without combination therapy" than was reported in the original, FDA-approved Eliquis label. SAC ¶ 65. That is not the case.

With regard to the bleeding risk associated with Eliquis use alone (rather than part of a combination therapy regimen), the ISMP report does not include any statements or data suggesting that the risk is higher than that reported in the labeling. Nor do Plaintiffs point to any such data in their complaint. On the contrary, the report states that Eliquis "showed the strongest safety profile," "accounted for the fewest reports and the fewest patient deaths both before and after adjusting for patient exposure," and "had the best adverse event safety profile by several

[2] Plaintiffs' SAC includes reference to all four documents, as well as the Eliquis label and FDA's Medical Review. *See* SAC ¶¶ 35, 41, 52-70. The Court may take notice of the entirety of the documents referenced in the complaint. *See Becker v. Cephalon, Inc.*, No. 14 Civ. 3864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015).

measures." Ex. 1 (ISMP QuarterWatch), at 2, 12. To be sure, Plaintiffs contend that the report found that "the risk of a bleeding event was increased by 1.58 fold for a patient on Eliquis compared to a patient on the venerable warfarin blood thinner."[3] SAC ¶ 58. But the data Plaintiffs cite in support of this claim relate to the incidence of adverse events of "embolic-thrombotic events," which are ischemic strokes, not bleeding events. *Id.* ¶ 57. Data on ischemic stroke, even if reliable, could not form the basis for a CBE label change related to bleeding risk.

With regard to the bleeding risk associated with Eliquis when used in combination with another therapy, Plaintiffs point to a single sentence from the ISMP report which states that "In the adverse event data, we found *that concomitant therapy with platelet inhibitors while taking anticoagulants* increased the odds of a hemorrhage event by threefold (OR 3.01 $p < 0.01$)," which Plaintiffs claim "is higher than what is indicated in the Eliquis label (See Eliquis Label, Sec. 7.3: Drug Interaction)." *Id.* ¶¶ 59-60 (emphasis added). To the extent Plaintiffs contend that this sentence could be the basis for a CBE, such claim fails for numerous reasons.

First, the original FDA-approved Eliquis label already prominently warns about the increased bleeding risk when Eliquis is taken in combination with antiplatelet agents. Section 7.3 of the label is titled "Anticoagulants and Antiplatelet Agents" and specifically states that "Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding." Ex. 5 (2012 Label), at 10. The very next sentence reports the results from the APPRAISE-2 clinical trial, in which subjects were treated with Eliquis in combination with antiplatelet agents. *See id.* In that trial, the incidence of major bleeding was

[3] While Plaintiffs describe warfarin as a "venerable" medication, the ISMP takes a starkly different view: "Warfarin, by a large margin, was the highest risk outpatient medical treatment in older patients, accounting for one-third of all emergency room visits . . . Most warfarin adverse events were for hemorrhages. A drug that substantially reduced warfarin bleeding events that could injure 16-20% of patients per year would be a major advance in drug safety." Ex. 1 (ISMP QuarterWatch), at 10. Eliquis has been shown to reduce the risk of major bleeding events by 31% compared to warfarin. Ex. 5 (2012 Label), at 7.

2.77% per year in patients treated with Eliquis plus an antiplatelet agent compared with 0.62% per year in patients treated with placebo (a sugar pill) plus an antiplatelet agent. *See id.* That translates to approximately a 4-fold higher incidence rate in patients receiving combination therapy, a ratio *greater than that quoted in the ISMP report*. Accordingly, the ISMP analysis cited by Plaintiffs does not provide evidence that the bleeding risk with Eliquis is of "a different type or greater severity or frequency" than previously included in submissions to FDA and reported in the Eliquis label, as required under the CBE regulation. 21 C.F.R. § 314.3(b).

Second, the risk estimate cited by Plaintiffs is not specific to Eliquis,[4] but rather is based on combined adverse event data from a number of anticoagulant medications, including warfarin. *See* Ex. 1 (ISMP QuarterWatch), at 12. As such, the estimate does not provide reliable information about the incidence of bleeding events in patients taking Eliquis in combination with an antiplatelet agent, and it cannot be directly compared to the incidence rates reported in the Eliquis label, which come from clinical trials specifically evaluating Eliquis.

Third, the risk estimate is based on an analysis of spontaneous adverse event reports, not on data from a controlled clinical trial or observational study. *See id.* It is well-recognized that analyses of spontaneous adverse event data, which lack a control group, have numerous limitations and provide far less reliable data than controlled studies. *See, e.g.*, *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (holding that spontaneous adverse event reports offer "one of the least reliable sources to justify opinions about both general and individual causation"). Indeed, FDA has specifically stated that such data "cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population." *See* Ex. 6 (Questions and Answers on FDA's Adverse Event Reporting System), at 2. For this reason

[4] Although the authors reported that "[t]he increased risk was found across all three of the novel anticoagulants and warfarin," the authors did not provide any specific risk estimate for Eliquis, and, as discussed above, the authors noted that the event rates for Eliquis were lower than for other anticoagulants. *See* Ex. 1 (ISMP QuarterWatch), at 12.

also, the ISMP analysis cannot provide reliable information about the incidence of bleeding events in patients taking Eliquis in combination with antiplatelet therapy.[5]

Fourth, Plaintiffs do not allege that Mr. Utts was taking Eliquis in combination with an antiplatelet agent such as aspirin or Plavix. Accordingly, any potential labeling changes based on an analysis of adverse event reports in patients taking combination therapy have no connection to Plaintiffs' litigation claims.[6] For all these reasons, the ISMP QuarterWatch Report does not provide any new information that could have supported independent changes to the warnings included in the Eliquis label.

The BMJ Article Concludes that the Bleeding Risk Associated with Eliquis Use in Real World Practice Is Consistent with that Observed in Pre-Approval Studies Considered by FDA. Plaintiffs state that a 2016 observational study published in the British Medical Journal reported that "NOACs were not significantly different from warfarin" in terms of their efficacy for reducing stroke risk. SAC ¶ 66. It is true that the study did not find a significant difference in ischemic stroke risk when patients taking Eliquis were compared with those taking warfarin. *See* Ex. 2 (Larsen 2016), at 6, fig. 2. That finding is consistent with the data reviewed by FDA and

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[5] For this same reason, spontaneous adverse event data cited by Plaintiffs, *see* SAC ¶¶ 53-56, do not provide reliable information about the incidence of such events and cannot form the basis of a CBE label change, particularly in the face of the extensive warnings related to bleeding risk already included in the FDA-approved Eliquis label.

[6] Plaintiffs also highlight the fact that the ISMP report notes that an Eliquis trial in patients with Acute Coronary Syndrome "was stopped because of excess bleeding and no identifiable benefits." SAC ¶ 64. The significance of this is unclear given that Mr. Utts does not allege that he was being treated with Eliquis for "acute coronary syndrome," but rather for atrial fibrillation. *See id.* ¶ 15. Moreover, the results of the trial were reviewed by FDA and discussed in the original Eliquis label: "APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo." Ex. 5 (2012 Label), at 10. As such, the trial does not provide any new information that could support a label change pursuant to the CBE regulation. Further, Eliquis is not approved for the treatment of acute coronary syndrome, and, thus, no basis exists to include specific warnings about potential risks for this indication.

reported in the Eliquis label. *See* Ex. 5 (2012 Label), at 19 ("Superiority to warfarin was primarily attributable to a reduction in hemorrhagic stroke and ischemic strokes with hemorrhagic conversion compared to warfarin. Purely ischemic strokes occurred with similar rates on both drugs."). Furthermore, as noted above, the relative reduction in ischemic stroke risk has no bearing on bleeding risk.

Further, Plaintiffs fail to mention the key, relevant findings from the study. Specifically, the authors found that "[t]he risks of death, any bleeding, or major bleeding were significantly lower for [Eliquis] . . . compared with warfarin" and noted that the "risks for any bleeding or major bleeding" with Eliquis in the study were "consistent with the results of the NOAC phase 3 clinical trial [ARISTOTLE]." *See* Ex. 2 (Larsen 2016), at 1, 8. The authors further concluded that all novel anticoagulants, including Eliquis, "seem to be safe and effective alternatives to warfarin." *Id*. at 1. Given these consistent findings, the article provides no new information that would support any changes to the warnings contained in the original FDA-approved labeling.

The JAMA Internal Medicine Article Discusses Data Considered by FDA Prior to Approving Eliquis. In their SAC, Plaintiffs cite to a 2015 JAMA Internal Medicine article authored by a journalism professor at NYU. *See* SAC ¶ 68; Ex. 3 (Seife 2015), at 1. Plaintiffs state that the article "critiqu[es] the ARISTOTLE study and Defendants' promotions and claims of the reduced mortality benefit of Eliquis when opposed to Warfarin," focusing in particular on alleged issues at a single research site in China. *See* SAC ¶ 68. While ARISTOTLE is discussed briefly, the article does not provide a new analysis of ARISTOTLE data, nor does it address the bleeding risk associated with Eliquis use. Instead, the commentary focuses on questions raised at the time of original approval about the observed mortality *benefit* with Eliquis, and acknowledges that FDA specifically considered the issue prior to approving the medication and approved the label as written. *See* Ex. 3 (Seife 2015), at 570, 574. As this Court noted in its

Order, data previously considered by FDA, including specifically the ARISTOTLE study, does not constitute "newly acquired information." Order, at 26, 30-31. Accordingly, the JAMA Internal Medicine article does not provide a basis for a CBE labeling change.

The FDA Signal Report Relates to a Potential Risk of Vasculitis, Not to the Bleeding Risk Associated with Eliquis Use. Plaintiffs also allege that "FDA itself is conducting a study only recently begun in November 2016, involving investigation into the strong adverse event signal connection between Eliquis and vasculitis." SAC ¶ 69. The citation points to an FDA website, which states that FDA has identified a potential signal in its adverse event database ("FAERS") for a number of different medications, including a potential signal for vasculitis in patients taking the novel anticoagulants Eliquis, Pradaxa, Savaysa, and Xarelto. *See* Ex. 4 (FDA Signal Report), at 1. That potential signal was identified based on an analysis of adverse event reports that occurred between July and September 2016. *See id*. As an initial matter, the potential signal relates to vasculitis, which is not characterized by bleeding and has not been alleged as an injury by Plaintiffs. *See* Ex. 7 (National Institutes of Health, "What is Vasculitis?"). Furthermore, the website states only that the Agency "is evaluating the need for regulatory action"; no further details are provided, and the website does not state that FDA has reached any conclusion as to whether an increased risk of vasculitis exists with Eliquis (or any of the other novel anticoagulants). *See* Ex. 4 (FDA Signal Report), at 1. Thus, at best, the report is a preliminary inquiry into a condition that is unrelated to Mr. Utts's alleged injury. It is not evidence that provides any basis to change the warnings about the bleeding risk with Eliquis.

C. Plaintiffs' Post-Approval Data Are Not Relevant to Their Warnings Claims.

Plaintiffs only purport to identify "newly acquired information" related to: (1) the risk of bleeding in patients taking combination therapy with an antiplatelet agent, (2) the relative stroke reduction when compared to warfarin, and (3) the risk of vasculitis. Plaintiffs do not identify any

new data relevant to the vast majority of labeling changes they seek, including specifically those relating to the availability of a reversal agent or antidote, the ability to assess or to measure Eliquis exposure, the "therapeutic range" of Eliquis, the methods for managing bleeding in patients taking Eliquis, the bleeding risk in aging patients, the need to monitor renal and hepatic function, the appropriate timing of stopping Eliquis before surgical procedures, the risks associated with head trauma, and the methods to adjust dosing.[7] *See* SAC ¶¶ 109, 135. Accordingly, the only warnings-based claims that plaintiffs have attempted to support are those relating to the risk of bleeding in patients taking combination therapy with antiplatelet agents.[8] But, as noted above, such claims bear no relationship to Plaintiffs' causes of action because Plaintiffs do not allege that Mr. Utts was treated with combination therapy. *See Knoppel v. St. Jude Med., Inc.*, Case No. SACV 13-383, 2013 WL 12116393, at *5 (C.D. Cal. Sept. 24, 2013) (dismissing failure-to-warn claims where plaintiffs had not alleged a "causal connection between Defendant's failed warnings and the alleged injuries"). "It would be a nonsensical result if a plaintiff could avoid a preemption defense by arguing that a drug label could have been strengthened in any form, regardless of its relevance to the plaintiff's case." *Cerveny v. Aventis, Inc.*, 155 F. Supp. 3d 1203, 1220 (D. Utah 2016).

In sum, the "Post-Approval Data" cited by Plaintiffs does not constitute "newly acquired

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[7] To the extent Plaintiffs suggest that the Defendants should have included a "Boxed" warning (*see* SAC ¶¶ 102-103, 109(n), 135(o)) or added information to the Medication Guide (*see id.* ¶¶ 109(q), 135(r)), FDA regulations prohibit making such changes via the CBE process. *See* 21 C.F.R. § 314.70(b)(2)(v); *see also Dopson-Troutt v. Novartis Pharms. Corp.*, 975 F. Supp. 2d 1209, 1219 (M.D. Fla. 2013) (holding that FDA regulations prohibit manufacturers from changing boxed warnings absent FDA approval); *Ray v. Allergan, Inc.*, Civ. A. No. 3:10CV136, 2012 WL 2120018, at *7 (E.D. Va. June 1, 2012) (same). Because such changes cannot be made through the CBE process, they are preempted. Likewise, any claims suggesting that Eliquis should be withdrawn from the market are preempted under *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013). *See also* Order, at 23-24.

[8] *See* SAC ¶¶ 109(u), 135(v) only. There are no allegations that Defendants failed to warn about the risk of vasculitis or about the relative risk reduction for ischemic stroke.

information" that could have supported independent changes to the warnings in the Eliquis label. Accordingly, Plaintiffs' warnings claims, which underlie each of their ten causes of action, are preempted and should be dismissed with prejudice.

II. The Warnings in the Eliquis Label Are Adequate as a Matter of Law.

In its December 23, 2016 Order, the Court deferred ruling on Defendants' argument that the Eliquis label is adequate as a matter of law, reserving that issue until it had an opportunity to make a final determination on preemption. Order, at 32. As discussed above, Plaintiffs have not come forward with any "newly acquired information" that would support independently making any changes to the information and warnings in the Eliquis labeling, which was carefully reviewed and subsequently approved by FDA. As such, Plaintiffs' claims regarding alleged deficiencies in the Eliquis label are preempted and should be dismissed.

In the event the Court declines to dismiss on preemption grounds, the Court should nonetheless dismiss Plaintiffs' warnings claims because the Eliquis label is adequate as a matter of law. As discussed in the opening brief, the label always has warned "in plain and explicit terms" of the very injury alleged by Plaintiffs, *Dash v. Roche Labs.*, 74 F.3d 1245, in particular emphasizing that Eliquis "can cause serious, potentially fatal bleeding" and that "[t]here is no established way to reverse the anticoagulant effect of apixaban." Ex. 5 (2012 Label), at 1, 5.

Plaintiffs list additional details about the alleged warnings deficiencies in a section of their SAC titled "Post-Approval Clinical Concerns Regarding Eliquis and Its Labeling."[9] *See* SAC ¶¶ 71-101. Plaintiffs specifically focus on claims related to "stopping bleeding events," "one size fits all method of prescribing," "surgery and lack of warnings or data," and, to a lesser extent, the risk of bleeding with head trauma and the lack of a reversal agent. *Id.* Based on these

[9] Plaintiffs made numerous misstatements about the labeling in their First Amended Complaint, which they have attempted to correct in their Second Amended Complaint. These changes do not alter the fact that Plaintiffs have not identified any deficiencies in the Eliquis labeling.

allegations, Plaintiffs conclude that "the warning label for Eliquis is inadequate." *Id*. ¶ 102. However, in each case, Plaintiffs' allegations are at odds with the plain language of the Eliquis label and/or are predicated on design defect claims this Court already has held were preempted. *See In re Yukos Oil Co. Sec. Litig.*, 2006 WL 3026024, at *12 (a court need not accept as true allegations that are contradicted by documents subject to judicial notice); Order, at 34-35.[10]

"Stopping Bleeding Events." Plaintiffs state that "Defendants apparently cannot be bothered to detail specific information how to stop a potentially life threatening bleeding event in their clinical information," and they criticize Defendants for not providing more definitive statements about the clinical utility of specific treatment strategies. SAC ¶¶ 74-75. Plaintiffs fail to mention, however, that the original, FDA-approved label includes a detailed discussion of potential methods for managing bleeding in patients taking Eliquis, which is prominently located in the Warnings & Precautions section of the label, under the heading Bleeding:

> There is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for about 24 hours after the last dose, i.e., for about two half-lives. A specific antidote for ELIQUIS is not available. Because of high plasma protein binding, apixaban is not expected to be dialyzable [see Clinical Pharmacology (12.3)]. Protamine sulfate and vitamin K would not be expected to affect the anticoagulant activity of apixaban. There is no experience with antifibrinolytic agents (tranexamic acid, aminocaproic acid) in individuals receiving apixaban. There is neither scientific rationale for reversal nor experience with systemic hemostatics (desmopressin and aprotinin) in individuals receiving apixaban. Use of procoagulant reversal agents such as prothrombin complex concentrate, activated prothrombin complex concentrate, or recombinant factor VIIa may be considered but has not been evaluated in clinical studies. Activated oral charcoal reduces absorption of apixaban, thereby lowering apixaban plasma concentration [see Overdosage (10)].

Ex. 5 (2012 Label), at 5. This warning reflects the data available on the topic and is consistent with the Australian recommendations that Plaintiffs cite in their SAC.[11] *See* SAC ¶ 73. In

[10] Defendants refer the Court to its original motion for additional information and argument as to the adequacy of the warnings in the Eliquis labeling regarding bleeding generally. *See* Ex. 8 (Defendants' Motion to Dismiss), at 11-14.

[11] It is worth noting that the Australian guidelines cited by Plaintiffs state that Eliquis

particular, like the Australian guideline, the Eliquis labeling recommends the use of activated oral charcoal to reduce apixaban concentration and advises physicians to consider the use of prothrombin complex concentrate ("PCC") and recombinant factor VIIa. *Id*. Further, the Eliquis label prominently warns "[t]here is no established way to reverse the anticoagulant effect of apixaban." Ex. 5 (2012 Label), at 5. Plaintiffs provide no basis for the Court to conclude that this accurate recital of the scientific knowledge regarding the management of bleeding in patients taking Eliquis is insufficient.

"One size fits all" Dosing. In their SAC, Plaintiffs acknowledge for the first time that Eliquis does not actually have "one size fits all" dosing. *See* SAC ¶¶ 91-92. Plaintiffs note that the FDA-approved Eliquis labeling provides for dose reduction in patients who are older, leaner, or who have impaired kidney function. *See id*. Dosing reduction is also recommended in patients who are on certain medications that may affect Eliquis metabolism. *See* Ex. 5 (2012 Label), at 2-3. Still, Plaintiffs suggest that "changing the method of monitoring to tailor the dosage of Eliquis seems to be a much safer alternative." SAC ¶ 94. Even assuming *arguendo* that this were true, Plaintiffs' allegation is a design defect claim (not a warnings claim), which is preempted pursuant to the Court's December 23 Order. Order, at 34-35. As such, it does not bear any relevance to the adequacy of the Eliquis labeling.

Surgery and Lack of Warnings or Data. Plaintiffs also claim that the Eliquis label does not contain sufficient information regarding "what to do if an Eliquis patient needs emergent surgery" and allege that "it is currently unknown what level of Eliquis would be considered safe for an elective surgery." SAC ¶¶ 71, 96. Plaintiffs further suggest that the only information in the labeling relevant to this issue is the mention of "the half-life of apixaban in a non-warning context." *Id*. ¶ 96. That is not the case. On the third page of the Eliquis label, there is an entire

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demonstrated "a superior reduction in stroke and systemic embolism" and "resulted in significantly less major bleeding" compared to warfarin. Ex. 9 (Ward 2013), at 1-2.

section devoted to "Discontinuation for Surgery and Other Interventions," which states:

> ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be non-critical in location and easily controlled.

Ex. 5 (2012 Label), at 3. The label also explains that the half-life of Eliquis is "about 12 hours" and that "when the drug is stopped for surgery, anticoagulation persists for at least a day." *Id*. at 14. Further, Plaintiffs' claim also has no relationship to this litigation, as Plaintiffs do not allege that Mr. Utts had surgery at any point while he was taking Eliquis.[12]

Risk of Bleeding with Head Trauma. Plaintiffs further assert that Defendants failed to warn that patients who take Eliquis who experience "a head injury may suffer an unstoppable, and potentially fatal, internal bleeding event." SAC ¶ 99. This claim also is at odds with the Eliquis labeling. *First*, as noted above, the Eliquis label clearly warns that Eliquis "can cause serious, potentially fatal bleeding" and that "[t]here is no established way to reverse the anticoagulant effect of apixaban." Ex. 5 (2012 Label), at 1, 5. This is true regardless of the cause of the bleeding. *Second*, as Plaintiffs themselves acknowledge, the FDA-approved Medication Guide, which is part of the Eliquis labeling, specifically advises patients to "Call your doctor or healthcare provider right away if you fall or injure yourself, especially if you hit your head. Your doctor or healthcare provider may need to check you." *Id*. at 29. Moreover, warnings related to the bleeding risk with head trauma bear no relationship to this case, as Plaintiffs do not allege that Mr. Utts suffered head trauma or had a head bleed.

Lack of a Reversal Agent. Plaintiffs' SAC also includes a series of new allegations about a reversal agent (AndexXa) that is currently in development by a company known as

[12] Plaintiffs' claims also are preempted design defect claims under this Court's Order, as they are predicated on an alleged failure to develop and gain FDA approval for a test to measure Eliquis levels. *See* SAC ¶ 96 ("no test has been correlated with bleeding risk").

Portola. *See* SAC ¶¶ 78-81. While Plaintiffs state that Defendants cooperated with Portola in developing the reversal agent and acknowledge that the agent was recently rejected by FDA, they make the somewhat bizarre claim that the Eliquis labeling is defective because "[n]o mention of this antidote is made." *Id*. ¶ 78. It is not clear what Plaintiffs expect Defendants to say in their labeling about an agent that has not been approved by FDA, particularly given that the labeling already prominently states that no reversal agent or antidote is available for patients taking Eliquis. Likewise, Plaintiffs complain that the labeling does not mention that Pradaxa, another novel oral anticoagulant, has an FDA-approved antidote. Even if FDA allowed Defendants to include comparative information in the Eliquis labeling about a different medication, the reversal agent for Pradaxa was approved in October 2015, more than a year after Mr. Utts's alleged injury. *See* Ex. 10 (FDA News Release). As such, any information about the reversal agent could not have had any impact on Mr. Utts's physician's prescribing decision.

In sum, the Eliquis label "clearly and explicitly warned" Mr. Utts's physician about the specific adverse event allegedly suffered by Plaintiff (internal bleeding) and addressed the very issues Plaintiffs now claim made the labeling inadequate. *Dash*, 74 F.3d at 1245. While Plaintiffs' complaint includes ten separate causes of action, the gravamen of each is that Defendants failed to adequately warn about the bleeding risk associated with Eliquis use and about the lack of a reversal agent. Because the warnings in the Eliquis label are adequate as a matter of law, Plaintiffs' warnings claims should be dismissed with prejudice.

III. Each Cause of Action in Plaintiffs' Second Amended Complaint Should Be Dismissed for Independent Reasons.

In addition to preemption and the adequacy of the Eliquis label, each of which dispose of the SAC in its entirety, Plaintiffs' individual causes of action also fail for independent reasons.

A. Plaintiffs Fail to State a Cause of Action for Manufacturing Defect.

In its December 23, 2016 Order, the Court stated that Plaintiffs' "complaint fails to

identify or explain how the product ingested by Mr. Utts either deviated from the defendants' intended result/design or from other seemingly identical product models." Order, at 36. On this basis, the Court dismissed the manufacturing defect claim, with leave to amend. Plaintiffs have since amended their complaint twice, but still have not come forward with any allegations as to how the Eliquis pills Mr. Utts took deviated from the design approved by FDA. *See* SAC ¶¶ 119-132. Accordingly, Plaintiffs' manufacturing defect claim (1st COA) should be dismissed.

B. Plaintiffs' Strict Liability and Negligence Claims Are Inadequately Pled.

Plaintiffs assert three causes of action premised on an alleged failure to warn about the bleeding risk associated with Eliquis use and the lack of a reversal agent: Failure to Warn (2nd COA), Strict Liability (3rd COA), and Negligence and Gross Negligence (4th COA).[13] *See* SAC ¶¶ 147, 164, 193. As discussed above, all of Plaintiffs' warnings claims fail because they are preempted by federal law and because the warnings in the Eliquis label are adequate as a matter of law. *See supra* at 4-17. Plaintiffs' claims also fail because the SAC does not provide sufficient facts for the Court to infer that "no warning was provided or the warning was inadequate" and "that the inadequacy or absence of the warning caused the plaintiff's injury." *See Motus v. Pfizer*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); *see also Plummer v. Lederle Labs.*, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law).

Plaintiffs offer a laundry list of alleged problems with the Eliquis label, including, for example, failure to warn "about the true safety risks associated with the use of Eliquis," SAC ¶ 135(c); "that there is no drug, agent, or means to reverse the anticoagulation effects of Eliquis during an expanded timetable," *id.* ¶ 135(f); "the increased risk of gastrointestinal bleeds," *id.*

[13] To the extent Plaintiffs allege that Defendants failed to adequately test Eliquis, such claims fail because no independent duty to test exists under California law. *See Phillippi v. Stryker Corp.*, No. 2:08-CV-02445, 2010 WL 2650596, at *2 (E.D. Cal. July 1, 2010), *aff'd*, 471 F. App'x 663 (9th Cir. 2012). Furthermore, allegations related to the design of Eliquis should be stricken pursuant to the Court's December 23, 2016 Order. *See, e.g.*, SAC ¶¶ 152, 153.

¶ 135(j); "the need to assess renal [and] hepatic functioning," *id*. ¶ 135(k, n); the need to "monitor [] patients closely for signs of neurological impairment," *id*. ¶ 135(l); and "the need for more comprehensive, more regular medical and blood monitoring." *Id*. ¶ 135(t). Missing, however, are specific *facts* that would support an inference that these alleged labeling deficiencies caused the warnings in the Eliquis label to be inadequate and, perhaps more importantly, that changing the labeling (to the extent that Defendants could have done so independent of FDA) would have prevented Mr. Utts from suffering internal bleeding. For this reason also, Plaintiffs' strict liability and negligent failure-to-warn claims should be dismissed.[14]

C. Plaintiffs' Causes of Action for Breach of Warranty Are Inadequately Pled.

Despite multiple opportunities, Plaintiffs still fail to correct the pleading deficiencies that led the Court to dismiss their warranty claims. As the Court noted in its Order, Plaintiffs' original complaint only included vague allegations that were insufficient to support their warranty claims. *See* Order, at 38, n. 9. With regard to express warranty claims, the Court found that Plaintiffs "d[id] not identify the express warranties on which this claim relies, including whether they appeared in the labeling and package inserts for the drug, which were approved by

[14] To the extent Plaintiffs allege that Defendants "overpromoted" Eliquis, *see* SAC ¶¶ 195(f), 213(e), such claim also fails. In support of these claims, Plaintiffs point to four advertisements, two that aired in 2013-2014 and two that aired in 2015-2016. *Id*. ¶¶ 44-45. As a threshold matter, allegations regarding commercials from 2015 and 2016 could not have had any impact on Mr. Utts's decision to take Eliquis because they aired after his alleged injury. As to commercials in 2013 and 2014, Plaintiffs allege that they included assertions that "Eliquis reduced the risk of stroke more effectively than warfarin, than [*sic*] Eliquis was safer than warfarin, and that unlike [warfarin], the blood levels of the patient did not need to be monitored." *Id*. ¶ 44. To the extent that such claims were made, they are consistent with the FDA-approved Eliquis label, which notes that, in the ARISTOTLE trial, Eliquis (a) was shown to be "superior to warfarin for the primary endpoint of reducing the risk of stroke and systemic embolism" and (b) "showed significantly fewer major bleeds than warfarin." Ex. 5 (2012 Label), at 19. Further, Eliquis was approved by FDA without the need for monitoring, and the labeling explicitly states that standard blood tests are "not useful in monitoring the anticoagulation effect of apixaban" and that the Rotachrom® assay "is not recommended for assessing the anticoagulant effect of apixaban" in clinical practice. *Id*. at 13. Plaintiffs also do not allege that Mr. Utts saw, or relied on, these commercials in deciding to take Eliquis.

the FDA, whether they appeared in an advertising campaign for the drug, or how the particular warranty was breached." *Id*. at 38. Likewise, with regard to the implied warranty claims, the Court noted that Plaintiffs only included broad fitness and merchantability claims that "appear to be challenging . . . the FDA's approval of Eliquis for sale to consumers." *Id*. at 39.

The allegations in the SAC do not materially differ from those in the original complaint. Plaintiffs claim broadly that Defendants warranted that "Eliquis was [] safe and efficacious for its intended uses," "was not unreasonably dangerous," was "fit for its intended use," "had been fully and adequately tested for long-term use," was "safe to use in the treatment of atrial fibrillation," "was a safe and effective product to be used as a blood thinner," "was safe and effective to use without the need for blood monitoring and dose adjustments," "was safe and of merchantable quality," and "was fit for use for the ordinary purposes." *See* SAC ¶¶ 205, 208, 209, 225. Plaintiffs do not otherwise provide any detail as to "the contents of any specific warranty or breach thereof," where such warranty appeared (other than generally pointing to labeling and direct-to-consumer advertising), or how it was made.[15] *Wendell v. Johnson & Johnson*, No. C 09-04124, 2010 WL 271423, at *5 (N.D. Cal. Jan. 20, 2010). Accordingly, Plaintiffs' warranty claims (5th and 6th COA) should be dismissed with prejudice.

D. Plaintiffs' Fraud Causes of Action Fail As a Matter of Law.

Pursuant to Fed. R. Civ. P. 9(b), allegations of fraud and misrepresentation must be pled with particularity, and must specifically include information about the nature, format, and content of the alleged representation or omission. Plaintiffs have now had three opportunities to

[15] Plaintiffs suggest generally that the representations were made in Eliquis labeling and in direct-to-consumer advertising. *See* SAC ¶ 207 ("Defendants expressly warranted in their labeling, product insert [and] via direct to consumer advertising (as noted above) that Eliquis was safe and effective"); *id*. ¶ 211 ("Defendants expressly represented . . . that the side effects [Eliquis] did produce were accurately reflected in the warnings"). To the extent plaintiffs rely on statements made in the labeling, such claims are preempted for the reasons discussed above. And, to the extent Plaintiffs point to representations in consumer advertisements, those allegations fail for the reasons discussed in footnote 14 above.

plead their fraud claims, but still have not done so with the specificity required by Rule 9(b). For this and other reasons, their fraud causes of action should be dismissed.

1. Fraud on the FDA Claims Are Preempted.

In its December 23, 2016 Order, this Court held that all fraud claims "premised on the interaction between the defendants and the FDA . . . are preempted and dismissed with prejudice." Order, at 42. Despite this ruling, Plaintiffs' Second Amended Complaint still contains numerous allegations related to alleged fraud on the FDA. *See* SAC ¶ 241 ("Defendants falsely and fraudulently represented to . . . the FDA"); ¶¶ 241(a-c) ("All of this data was fraudulently submitted to the FDA"); ¶ 252 ("Defendants . . . withheld information from the FDA which they were required to report"); ¶ 270 ("Defendants breached their duty in representing Eliquis' serious side effects to . . . the FDA"). These fraud-on-the-FDA allegations should be stricken.

2. Plaintiffs' Fraud Claims Are Inadequately Pled.

In their amended complaints, Plaintiffs identified several documents which they contended contain fraudulent misrepresentations and omissions. *See* SAC ¶ 241. These include three pages from the Eliquis.com website, a Dosing Guideline from March 2014, a package insert from December 2012, and a package insert from March 2014. As discussed below, the statements Plaintiffs point to in these documents are insufficient to support a cause of action for fraud under the heightened pleading standards of Rule 9(b).

December 2012 and March 2014 Package Inserts. Plaintiffs allege that the December 2012 and March 2014 package inserts contained fraudulent representations and omissions regarding the dosing of Eliquis and the bleeding risk associated with the lack of a reversal agent. *See* SAC ¶¶ 241(e-f). These claims are nothing more than failure-to-warn allegations repackaged as fraud claims. Absent "newly acquired information," Defendants no more could have independently changed the March 2014 label than they could have changed the original,

FDA-approved label issued in December 2012. As discussed above, Plaintiffs have not identified any "newly acquired information" that could have supported an independent change to the dosing recommendations or the warnings about the bleeding risk, and they provide no allegations to support a claim that the representations in these labels were fraudulent in any way. Accordingly, Plaintiffs' allegations are preempted and should be stricken.

March 2014 "Dosing Guidelines". Plaintiffs allege that the March 2014 "Dosing Guidelines," which are provided to physicians as a reference to help reinforce the dosing information included in the Eliquis label, "misled prescribing physicians and consumers to believe" that Eliquis was safe for use in patients with moderate or severe renal impairment and that no routine monitoring is necessary. *See* SAC ¶ 241(d). Plaintiffs base this claim on two statements in the guidelines: that "[n]o dose adjustment [is] required in patients with mild, moderate, or severe renal impairment" and that Eliquis "[d]oes not require routine monitoring using international normalized ratio[] (INR) or other tests of coagulation." *Id*. These statements, however, are consistent with the FDA-approved Eliquis labeling. *See* Ex. 5 (2012 Label), at 17, Fig. 3 (stating that "no dose adjustment" is required for patients with mild, moderate, and severe renal impairment); *id*. at 13 (stating that INR and other coagulation tests are "not useful in monitoring the anticoagulation effect of apixaban"). Plaintiffs have not alleged any facts to suggest that those statements are incorrect, that Defendants knew those statements to be incorrect, or that Defendants acted fraudulently in any other way.

Furthermore, because any documents that provide information about medication dosing are considered by FDA to be labeling, the information included in the guidelines must be consistent with the FDA-approved Eliquis label. *See* 21 C.F.R. § 201.100(d); *see also Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 394 (6th Cir. 2013). Because Plaintiffs have not identified any data that would have supported any change to the FDA-approved dosing recommendations,

Plaintiffs' claims based on the contents of the Dosing Guidelines are preempted.

Eliquis.com Website. Plaintiffs also claim that Defendants made three fraudulent representations on the Eliquis.com website: (1) that Eliquis was proven effective for nonvalvular atrial fibrillation in Phase III studies, *see* SAC ¶ 241(a), (2) that Eliquis is the only anticoagulant that demonstrated superiority in both stroke and systemic embolism and major bleeding versus warfarin, *see id*. ¶ 241(b), and (3) that Eliquis had less major bleeding than warfarin and did not require routine monitoring, *see id*. ¶ 241(c). Each of those representations is true and consistent with FDA's medical review and the FDA-approved label. *First*, Eliquis was approved by FDA as safe and effective for the treatment of nonvalvular atrial fibrillation, based on the results of its Phase III studies.[16] *See* Ex. 5 (2012 Label), at 2, 18-23. If FDA had not concluded that Eliquis was effective for this indication, it would not have approved the medication.[17] *Second*, FDA's pre-approval medical review concluded that Eliquis "was superior to warfarin for the primary efficacy and safety endpoints as well as mortality" and approved a label that states that Eliquis "was superior to warfarin for the primary endpoint of reducing the risk of stroke and systemic embolism . . . [and] showed significantly fewer major bleeds than warfarin." Ex. 11 (Apixaban Medical Reviews), at 54; Ex. 5 (2012 Label), at 19. *Third*, while warfarin requires routine monitoring, FDA approved Eliquis without the need for monitoring.

In sum, none of the statements discussed above provide an adequate factual basis for

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[16] FDA carefully evaluated the conduct of ARISTOTLE prior to approving Eliquis. *See* Ex. 11 (Apixaban Medical Reviews), at 3-5, 53-73, 119-20, 124-26, 180-86. FDA determined that concerns related to the conduct of the trial had been addressed by BMS and did not affect the overall outcomes of the study or FDA's conclusions about the safety and efficacy of Eliquis. *Id*. After completing its review, FDA approved for inclusion in the Eliquis label a summary of the ARISTOTLE results, which Plaintiffs now describe as fraudulent. As noted earlier, any claims premised on alleged fraud on the FDA are preempted under *Buckman*, and any claims related to the original FDA-approved label are preempted as well.

[17] FDA only may approve a drug if it finds that the drug "is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof" and "will have the effect it purports or is represented to have." 21 U.S.C.A. § 355(d)(1-5).

Plaintiffs' fraud claims. Furthermore, Plaintiffs do not allege which, if any, of the statements were seen and relied on by Mr. Utts's physician at the time he prescribed Eliquis. *See Hawkins v. Medtronic*, No. 1:13-CV-00499, 2014 WL 346622, at *13 (E.D. Cal. Jan. 30, 2014) (dismissing fraud claims because plaintiff "fail[ed] to allege not only the content of the off-label promotion directed at his spine surgeon and on which the surgeon relied, but he also fail[ed] to allege who made those representations to his surgeon and when the representations were made"); *Mirkin v. Wasserman*, 858 P.2d 568, 571-72 (Cal. 1993) (rejecting "fraud-on-the-market" doctrine and holding that reliance is a required element of a fraud claim under California law). Accordingly, Plaintiffs' fraud / fraudulent concealment claims (7th COA) should be dismissed.

3. Plaintiffs' Negligent Misrepresentation Claims Are Inadequately Pled.

In their SAC, Plaintiffs still do nothing more than recite the elements of a claim for negligent misrepresentation. *See* SAC ¶¶ 264-76. Missing entirely is any detail as to the substance, nature, or circumstances of the alleged misrepresentations as required by Rule 9(b). *Ressler v. Liz Claiborne, Inc.*, 75 F. Supp. 2d 43, 52 (E.D.N.Y. 1998), *aff'd sub nom. Fishbaum v. Liz Claiborne, Inc.*, 189 F.3d 460 (2d Cir. 1999). Accordingly, Plaintiffs' negligent misrepresentation claims (8th COA) also should be dismissed.

E. Plaintiffs' Consumer Protection Cause of Action Is Inadequately Pled.

Plaintiffs allege that Defendants "engaged in unfair, deceptive, false and fraudulent acts and practices in violation of California law" by "[p]ublishing instructions and product material containing inaccurate and incomplete factual information," "[m]isrepresenting the nature, quality, and characteristics about the product," and "[e]ngaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding." SAC ¶¶ 279, 280. Such "[t]hreadbare recital[] of the elements of a cause of action, supported by mere conclusory statements" is entirely insufficient to maintain a claim for violation of California consumer protection laws.

Wendell v. Johnson & Johnson, 2010 WL 271423, at *2 (*quoting Aschroft*, 556 U.S. at 678). That is particularly true where, as here, the claims are premised on allegations of fraudulent conduct, which must be pled with particularity under Rule 9(b). *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). Accordingly, those claims (9th COA) should be dismissed.

F. Plaintiff Ciara Utts's Loss of Consortium Claim Is Derivative.

Under California law, an action for loss of consortium is derivative and "is, by its nature, dependent on the existence of a cause of action for tortious injury to a spouse." *LeFiell Mfg. Co. v. Super. Ct.*, 282 P.3d 1242, 1246 (Cal. 2012). Because all other counts fail as a matter of law, Mrs. Utts's loss of consortium claim (10th COA) also must be dismissed.

IV. Plaintiffs' Demand for Punitive Damages Should Be Denied.

Punitive damages are only recoverable where "it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." Cal. Civ. Code § 3294; *see also Taylor v. Super. Ct.*, 598 P.2d 854, 862 (Cal. 1979). Punitive damages are an "extraordinary" remedy, *see Dyna-Med, Inc. v. Fair Emp't & Hous. Comm'n*, 743 P.2d 1323, 1328 (Cal. 1987), and are only allowed in the "clearest of cases." *Woolstrum v. Mailloux*, 190 Cal. Rptr. 729, 734 (Cal. App. Dep't Super. Ct. 1983). To support an award of punitive damages, the conduct must be of "such severity or shocking character [as] warrants the same treatment as accorded to willful misconduct—conduct in which defendant *intends* to cause harm." *Id.* at 735. Here, Plaintiffs do not allege—with the particularity required under Rule 9(b)—that Defendants acted with malice or committed fraud such that an inference of intent to harm can be drawn. Accordingly, Plaintiffs' demand for punitive damages should be denied.

CONCLUSION

For the reasons stated above, and pursuant to Fed. R. Civ. P. 12(b)(6) and Fed. R. Civ. P. 9(b), Plaintiffs' Second Amended Complaint should be dismissed in its entirety.

Dated: New York, New York.
March 10, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Loren H. Brown, hereby certify that on March 10, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Loren H. Brown